

21 CFR 310.201

APRIL 1, 2003

limited to prescription sale under the provisions of section 503(b)(1) of the act.

(ii) The pamabrom and all other components of the preparation meet their professed standards of identity, strength, quality, and purity.

(iii) If the preparation is a new drug, an application pursuant to section 505(b) of the act is approved for it.

(iv) The preparation contains not more than 50 milligrams of pamabrom per dosage unit.

(v) The preparation is labeled with adequate directions for use in the temporary relief of the minor pains and discomforts that may occur a few days before and during the menstrual period.

(vi) The dosages recommended or suggested in the labeling do not exceed 50 milligrams of pamabrom per dose or 200 milligrams per 24-hour period.

(22) Diphehanil methylsulfate (4-diphenylmethylene-1,1-dimethyl-piperidinium methylsulfate) preparations meeting all the following conditions:

(i) The diphehanil methylsulfate is prepared, with or without other drugs, in a dosage form suitable for use in self-medication by external application to the skin, and containing no drug limited to prescription sale under the provisions of section 503(b)(1) of the act.

(ii) The diphehanil methylsulfate and all other components of the preparation meet their professed standards of identity, strength, quality, and purity.

(iii) If the preparation is a new drug, an application pursuant to section 505(b) of the act is approved for it.

(iv) The preparation contains not more than 2.0 percent of diphehanil methylsulfate.

(v) The preparation is labeled with adequate directions for use by external application to the skin for the relief of symptoms of mild poison ivy, oak, and sumac and other minor irritations and itching of the skin.

(vi) The directions for use recommend or suggest not more than four applications of the preparation per day, unless directed by a physician.

(vii) The labeling bears, in juxtaposition with the directions for use, a clear warning statement, such as: "Caution: If redness, irritation, swelling, or pain persists or increases, discontinue use and consult physician."

(23) Dyclonine hydrochloride (4-butoxy-3-piperidinopropiophenone hydrochloride; 4-n-butoxy-[beta]-piperidonopropiophenone hydrochloride) preparations meeting all the following conditions:

(i) The dyclonine hydrochloride is prepared, with or without other drugs, in a dosage form suitable for use as a cream or ointment in self-medication by external application to the skin, or rectally, and contains no drug limited to prescription sale under the provisions of section 503(b)(1) of the act.

(ii) The dyclonine hydrochloride and all other components of the preparation meet their professed standards of identity, strength, quality, and purity.

(iii) If the preparation is a new drug, an application pursuant to section 505(b) of the act is approved for it.

(iv) The preparation contains not more than 1.0 percent of dyclonine hydrochloride.

(v) The preparation is labeled with adequate directions for use:

(a) By external application to the skin for the temporary relief of pain and itching in sunburn, nonpoisonous insect bites, minor burns, cuts, abrasions, and other minor skin irritations.

(b) [Reserved]

(c) In the prevention or treatment of other minor conditions in

which it is indicated.

(vi) The labeling bears, in juxtaposition with the directions for use, clear warning statements against:

(a) Continued use if redness, irritation, swelling, or pain persists or increases, unless directed by a physician.

(b) Use in case of rectal bleeding, as this may indicate serious disease.

(c) Use in the eyes.

(d) Prolonged use.

(e) Application to large areas of the body.

(f) Use for deep or puncture wounds or serious burns.

(24) Chlorothen citrate (chloromethapyrilene citrate; N,N-dimethyl-N'-(2-pyridyl)-N'-(5-chloro-2-thenyl) ethylenediamine citrate) preparations meeting all the following conditions:

(i) The chlorothen citrate is prepared, with or without other drugs, in tablet or other dosage form suitable for oral use in self-medication, and containing no drug limited to prescription sale under the provisions of section 503(b)(1) of the act.

(ii) The chlorothen citrate and all other components of the preparation meet their professed standards of identity, strength, quality, and purity.

(iii) If the preparation is a new drug, an application pursuant to section 505(b) of the act is approved for it.

(iv) The preparation contains not more than 25 milligrams of chlorothen citrate per dosage unit.

(v) The preparation is labeled with adequate directions for use in the temporary relief of the symptoms of hay fever and/or the symptoms of other minor conditions in which it is indicated.

(vi) The dosages recommended or suggested in the labeling do not exceed: For adults, 25 milligrams of chlorothen citrate per dose or 150 milligrams of chlorothen citrate per 24-hour period; for children 6 to 12 years of age, one-half of the maximum adult dose or dosage.

(vii) The labeling bears, in juxtaposition with the dosage recommendations:

(a) Clear warning statements against administration of the drug to children under 6 years of age or exceeding the recommended dosage, unless directed by a physician, and against driving a car or operating machinery while using the drug, since it may cause drowsiness.

(b) If the article is offered for the temporary relief of symptoms of colds, a statement that continued administration for such use should not exceed 3 days, unless directed by a physician.

(25) [Reserved]

(26) Methoxyphenamine hydrochloride ([beta]-(o-methoxyphenyl)-isopropyl-methylamine hydrochloride; 1-(o-methoxyphenyl)-2-methylamino-propane hydrochloride) preparations meeting all the following conditions:

(i) The methoxyphenamine hydrochloride is prepared with appropriate amounts of a suitable antitussive, with or without other drugs, in a dosage form suitable for oral use in self-medication, and containing no drug limited to prescription sale under the provisions of section 503(b)(1) of the act.

(ii) The methoxyphenamine hydrochloride and all other components of the preparation meet their professed standards of identity, strength, quality, and purity.

(iii) If the preparation is a new drug, an application pursuant to section 505(b) of the act is approved for it.

(iv) The preparation contains not more than 3.5 milligrams of methoxyphenamine hydrochloride per milliliter.

OTC Ingredient List
Updated July 2003

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
dyclonine hydrochloride						
		external analgesic	fever blister (topical)	n/a	I	pending
		external analgesic	poison ivy/oak/sumac	n/a	I	pending
	hemorrhoidal	anorectal	anesthetic (external)	IIIE	I	346.10(e)
	hemorrhoidal	anorectal	anesthetic (intrarectal)	IIIE	IIIE	[55 FR 1779]
	oral cavity	oral health care	analgesic/anesthetic	I	I	pending
	topical analgesic	external analgesic	analgesic/anesthetic	I	I	pending
e. coli vaccines						
	hemorrhoidal	anorectal	anorectal (external)	IISE	IISE	310.545(a)(26)(vii)
	hemorrhoidal	anorectal	anorectal (intrarectal)	IISE	IISE	310.545(a)(26)(vii)
edetate disodium						
	contraceptive/vaginal	vaginal	minor irritations	IIIE	withdraw	n/a
	dental	relief of oral discomfort	tooth desensitizer (in combination only)	IISE	IISE	pending
edetate sodium						
	contraceptive/vaginal	vaginal	minor irritations	IIIE	withdraw	n/a
elaterin resin						
	laxative	laxative	stimulant laxative	IIS	IIS	310.545(a)(12)(iv)(A)
elecampane						
	miscellaneous internal	digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)